



PATENT

Case Docket No. CHMC7.001CP1

Date: July 23, 2001

Page 1

In re application of : Whitsett, J.  
App. No. : 09/558,576  
Filed : April 26, 2000  
For : SURFACTANT PROTEIN D  
FOR THE PREVENTION AND  
DIAGNOSIS OF PULMONARY  
EMPHYSEMA  
Examiner : Robinson, P.  
Art Unit : 1653

I hereby certify that this correspondence and all  
marked attachments are being deposited with the  
United States Postal Service as first class mail in  
an envelope addressed to: Assistant Commissioner  
for Patents, Washington, D.C. 20231, on

July 23, 2001

(Date)

James J. Mullen III, Ph.D., Reg. No. 44,957

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ASSISTANT COMMISSIONER FOR PATENTS  
WASHINGTON, D.C. 20231

Sir:

Transmitted herewith is an amendment in the above-identified application.

(X) An extension of time to respond for two month(s) is hereby requested.

Time Extension Fee:

(X) two months (\$195 small entity)

The fee has been calculated as shown below:

CLAIMS AS FILED						
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
Total Claims	7	—	28	= -0- ×	\$9	= \$-0-
Independent Claims	1	—	11	= -0- ×	\$40	= \$-0-
If application has been amended to contain multiple dependent claim(s), then add					\$135	= \$-0-
Time Extension Fee						\$195
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT						\$195

(X) The present application qualifies for small entity status under 37 C.F.R. § 1.27.

(X) Return prepaid postcard.

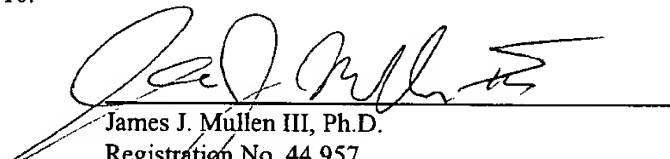
(X) A check in the amount of \$195 is enclosed.

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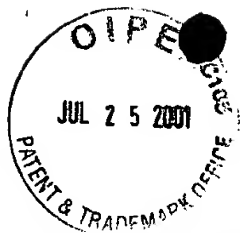
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- (X) Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.



James J. Mullen III, Ph.D.  
Registration No. 44,957  
Attorney of Record

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CHMC7.001CP1



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PATENT

#9  
VC  
8-1-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Whitsett, J.

Appl. No. : 09/558,576

Filed : April 26, 2000

For : SURFACTANT PROTEIN D  
FOR THE PREVENTION AND  
DIAGNOSIS OF  
PULMONARY EMPHYSEMA

Examiner : Robinson, P.

) Group Art Unit 1653

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) Commissioner for Patents, Washington, D.C.  
) 20231, on

July 23, 2001

(Data)  
  
James J. Mullen, III, Ph.D., Reg. No. 44,957

**RESPONSE**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Please consider the following Response to the Office Action mailed from the United State Patent and Trademark Office (PTO) February 21, 2001 (Paper No. 7). Applicant hereby requests a two-month extension of time for the present Response.

**REMARKS**

Claims 10 and 29-34 are pending. Claims 10 and 29-34 stand rejected. Applicants respectfully request withdrawal of the rejections.

**Rejection under 35 U.S.C. §102(e)**

Claims 10 and 30-32 stand rejected under 35 U.S.C. §102(e) as being anticipated by Tausch U.S. Patent No. 6,180,142 B1 (hereinafter, "the '142 patent"). More specifically, the PTO has alleged that the '142 patent teaches the treatment of pulmonary diseases using a composition containing SP-A, SP-B, SP-C, or SP-D, either individually or in combination. The

Appl. No. : 09/558,576  
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PTO has cited various passages in support of this allegation. (The '142 patent at Col. 1, line 56 to Col 2, line 20; Col 2, lines 38-43; and Col. 4, lines 2-9). Applicants respectfully disagree.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). The presently claimed invention is directed to "A pharmaceutical composition effective in treating pulmonary disease in mammals comprising: **SP-D protein** in admixture with a pharmaceutically acceptable excipient." Contrary to what the PTO alleges, at no point does the '142 patent teach a pharmaceutical composition containing SP-D.

The PTO has cited various passages to support the present rejection, none of the passages cited by the PTO teaches or mentions a pharmaceutical composition comprising SP-D. In fact, SP-D is mentioned only at Col. 4, lines 2-9. This passage reads as follows:

"A variety of animal derived surfactants are commercially available. Examples are as follows. In these examples, the terms "SP-A," "SP-B," "SP-C," and "SP-D" refer to four specific surfactant proteins that have been isolated from naturally occurring pulmonary surfactants and identified by researchers. The proteins are widely cited by these names in the published literature on pulmonary surfactants."

The passage then goes on to list and provide the contents of 11 published surfactants, none of which contains SP-D. Therefore, contrary to the PTO's statement, the '142 patent only teaches compositions containing SPA, SP-B, or SP-C individually or in combination. No composition containing SP-D is taught.

Because the '142 patent fails to teach a composition comprising SP-D, it cannot be said that the '142 patent teaches each and every limitation of the claimed invention. Accordingly, the pending claims are not anticipated by the '142 patent. Therefore, Applicants request withdrawal of the pending rejection.

#### **Rejection under 35 U.S.C. §103(a)**

Claims 10 and 29-34 were also rejected under 35 U.S.C. §103(a) as being unpatentable over the '142 patent in view of Arizumi et al., U.S. Patent No. 6,046,158 (hereinafter "the '158 patent"). To support a *prima facie* case of obviousness, one or more references must, *inter alia*, teach all of the elements recited in the pending claims. As discussed above, the '142 patent does not does not teach all of the claimed elements, as the '142 reference fails to teach a

Appl. No. : 09/558,576  
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pharmaceutical composition that comprises SP-D. Further, the Ariizumi reference does not ameliorate this deficiency of the '142 patent.

The '158 patent teaches the use of IL-4 and members of the C-type lectin family. The '158 patent does not teach the use of SP-D. Therefore, the combined references do not teach the claimed invention because they do not teach a pharmaceutical composition comprising SP-D.

Thus, the combination of Taeusch ('142 patent) and Ariizumi et al. ('158 patent) does not teach or suggest all of the elements of the claimed invention. Accordingly, applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103.

### Conclusion

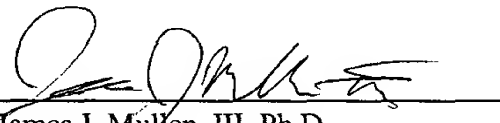
Should there be any questions in response to the above-identified patent application, the PTO is respectfully requested to contact the attorney at the number indicated below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 23 July 2001

By:   
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